REMARKS

Appreciation is hereby expressed to Dr. Grun for the interview so courteously granted on December 19, 2001. The Examiner is thanked for his courtesy and professionalism at the interview.

Pursuant to that interview, Claims 6 and 13 have been canceled and Claims 1, 2 and 3 rewritten along the lines discussed at the interview to more definitely set forth the invention and obviate the rejections under 35 U.S.C. §112.

Support for the amendment of Claims 1 and 2 can be found in the Specification on page 20, lines 21-25, page 9, 10 and 11, lines 1-13. Support for the amendment of Claim 3 can be found in the Specification on page 11, lines 14-25, page 12, and page 13, lines 1-3. The present amendment is deemed not to introduce new matter. Claims 1-3, 5, 9-12 and 14-16 remain in the application.

Reconsideration is respectfully requested of the rejection of Claims 1, 2, 5-6, 9-11 and 13 under 35 U.S.C. § 112, first paragraph. As indicated above, Claim 1 has been rewritten in the manner suggested by the Examiner. It is therefore believed that the rejection with respect to Claim 1 is moot. Claim 2 has been rewritten as an independent claim combining Claim 2 with the subject matter of Claim 1 as amended. It is therefore believed that the rejection of Claim 2 is likewise moot. The remaining claims 5, 9, 10, and 11 are dependent directly or indirectly upon Claim 1 and a rejection thereof is likewise believed to be moot. For this reason, it is respectfully submitted that the rejection is

now moot and withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 2, 3 and 11-16 under 35 U.S.C. § 112, second paragraph, as being indefinite. As indicated above, Claim 2 has been combined with Claim 1 and Claim 2 clearly differentiates from Claim 1 by indicating that a first reagent contains the insoluble carrier in (a) and the second reagent contains the enzyme inhibitor and substrate contained in (b) and (c). Claim 2 is believed to provide additional limitations to the subject matter of Claim 1.

As for Claim 3, this claim has been rewritten to spell out the interrelationships of the components and how components (b) and (c) contribute to the absorbence change and to the measurement and/or quantitative determination. It is believed that the amendment of Claim 3 obviates the rejection and that the rejection is now moot. Withdrawal of the rejection is accordingly respectfully requested.

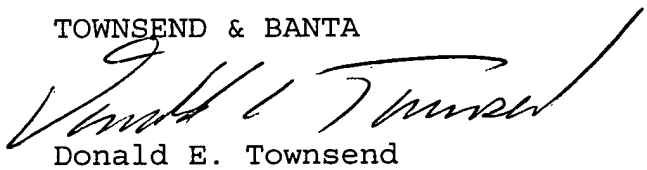
In summary, it is respectfully submitted that the amendments of the claims clarify the relationship between the components making up the immunoassay reagent and explain how the reactions occur and produce an optically detectable indication in quantitatively determining the presence and amount of a target antigen or antibody in a sample. For this reason, it is respectfully submitted that the rejection is no longer applicable to the claims now in the case and the Examiner would therefore be justified in no longer maintaining the rejection. Withdrawal of

the rejection is accordingly respectfully requested.

The application is now believed to be in condition for allowance and early action and allowance thereof is accordingly respectfully requested. If there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted

TOWNSEND & BANTA



Donald E. Townsend
Reg. No. 22,069

TOWNSEND & BANTA
1225 Eye Street, N.W.
Suite 500, #50028
Washington, D.C. 20005
(202) 682-4727

Date: May 28, 2002

MARKED UP VERSION OF AMENDED CLAIMS 1, 2, and 3

Please substitute the following amended Claims 1, 2 and 3 for the previously amended Claims 1, 2 and 3 as follows:

1. (Fourth Amended) An immunoassay reagent for use in a quantitative determination of a target antigen or antibody present in a sample, said reagent consisting essentially of the following components:

(a) [An] an insoluble carrier which carries and is coupled to an enzyme and an antibody or antigen reactive with said target antigen or antibody, said insoluble carrier comprising at least one selected from the group consisting of an organic polymer powder article, microorganism, blood cell and cell membrane fragment, said insoluble carrier being capable of aggregation;

(b) an enzyme inhibitor for reacting with and inhibiting activity of said enzyme [;], said enzyme inhibitor being in a free state uncoupled to an antigen or antibody and being increasingly unhindered from reacting with said enzyme when said insoluble carrier is increasingly agglutinated; and

(c) a substrate [with which the enzyme reacts] for the enzyme capable of producing an optically detectable indication of reaction with the enzyme, wherein said substrate is not hindered from reacting with said enzyme when said enzyme is unreacted with said enzyme inhibitor when said insoluble carrier is increasingly aggregated, said components (a) - (c) being maintained separate and apart and mixed together only with a sample containing the target

antigen or antibody.

2. (Twice Amended) An immunoassay reagent for use in a quantitative determination of a target antigen or antibody present in a sample, said reagent consisting essentially of the following components:

(a) an insoluble carrier which carries and is coupled to an enzyme and an antibody or antigen reactive with said target antigen or antibody, said insoluble carrier comprising at least one selected from the group consisting of an organic polymer powder article, microorganism, blood cell and cell membrane fragment, said insoluble carrier being capable of aggregation;

(b) an enzyme inhibitor for reacting with and inhibiting activity of said enzyme, said enzyme inhibitor being in a free state uncoupled to an antigen or antibody and being increasingly hindered from reacting with said enzyme once that insoluble carrier is increasingly agglutinated; and

(c) a substrate for the enzyme capable of producing an optically detectable indication of reaction with the enzyme, wherein said substrate is not hindered from reacting with said enzyme when said enzyme is unreacted with said enzyme inhibitor when said insoluble carrier is increasingly aggregated, said immunoassay reagent consisting of a first reagent and a second reagent [The immunoassay reagent as recited in claim 1], wherein [a] said first reagent contains said insoluble carrier in (a) above, and [a] said second reagent contains said enzyme inhibitor

and said substrate in (b) and (c) above.

3. (Fourth Amended) An immunoassay reagent for use in quantitative determination of a target antigen or antibody present in a sample, said reagent consisting essentially of the following components:

(a) an insoluble carrier which carries and is coupled to an enzyme inhibitor and an antibody or antigen reactive with said target antigen or antibody, said insoluble carrier comprising at least one selected from the group consisting of an organic polymer powder particle, microorganism, blood cell and cell membrane fragment, said insoluble carrier being capable of aggregation;

(b) an enzyme which reacts with and whose activity is inhibited by said enzyme inhibitor[;], said enzyme being in a free state uncoupled to an antigen or antibody and the reaction between the enzyme and enzyme inhibitor being dependent upon the amount of antigen or antibody present in a sample, and in the presence of an antigen or antibody the insoluble carriers are caused to aggregate, resulting in stearic hindrance of resulting aggregates and reduction of reactions between the enzyme and enzyme inhibitor on the insoluble carrier; and

(c) a substrate with which the enzyme reacts, said components (a)-(c) being maintained separate and apart and sequentially mixed together only with a sample of target antigen or antibody, the addition of the substrate facilitating reaction with the enzyme, thereby effecting an optically detectable change in absorbence.